DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 15, 2016

Sung Hwan E&B Company, Ltd
% Mr. Kachi Enyinna
510K Technology Group, LLC
263 Huntington Avenue, #332
Boston, Massachusetts 02115

Re: K150409
Trade/Device Name: VIVACE Electrosurgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OUH
Dated: November 30, 2015
Received: December 3, 2015

Dear Mr. Enyinna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150409

Device Name

VIVACE Electrosurgical System

Indications for Use *(Describe)*

The VIVACE Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. This Vivace Electrosurgical System is intended for use with Skin Type I to Skin Type V.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

I. Sponsor's Information

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Date Prepared: **January 6, 2016**

II. Device Name

Trade Name:	**VIVACE**
Common Name:	**Electrosurgical System and Accessories**
Classification Name:	**Electrosurgical Cutting and Coagulation device and Accessories**
Classification Number:	**21 CFR 878.4400**
Product Code:	**OUH**
Classification Panel:	**General and Plastic Surgery**

III. Predicate Device

The VIVACE Electrosurgical System is substantially equivalent to the INFINI Radiofrequency System (K121481).

IV. Intended Use

The VIVACE Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles. This Vivace Electrosurgical System is intended for use with Skin Type I to Skin Type V.

V. Device Description

The VIVACE Electrosurgical System is comprised of the following components: the system main body of the device which consists of the LCD touch screen control panel, the high frequency generating output section (main P.C.B board or RF Generator), and the power supply component, the Switching Power Supply (SMPS). The accessories to the device include the handpiece with disposable micro-needle cartridge (electrode) insertion, and foot switch. Radio frequency current (RF energy) is delivered from the RF Generator, through the handpiece and electrode tip into the target tissue. The hand piece being held at right angles, the tip is placed in light contact with the epidermis. As RF energy passes through the skin, it generates an electro thermal reaction, which is capable of coagulating (causing minor dermal damage) the tissue. The bi-polar RF energy is delivered between independent adjacent electrode pairs (total 36 needle electrode, 6 x 6 array insertion). The RF generator, hand piece are not disposable. Each disposable micro-needle cartridge (electrode) is supplied sterile and is for single patient use only and cannot be re-sterilized.

VI. Technical Specifications

Electrical voltage and frequency		**AC 230V 50/60 Hz**
Power conception		**40 VA**
Maximum output current		**62mA ± 20% (load resistance 500Ω**
Maximum output voltage		**134V ± 20% (load resistance 500Ω**
Accuracy of the output frequency		**1 MHz**
Microneedle Cartridge	**Electrode**	**36 each, 6 x 6 array**
	Exposed length	**0.5 ~ 3.5mm (0.1mm increments)**
	Outer diameter	**∅0.3mm**
Weight		
Dimension		**(W)380mm x (L)340mm x (H)1200mm**

VII. Performance Data

Electrical safety test, Electromagnetic compatibility test, Sterility, and Biocompatibility testing were completed to demonstrate the safety and performance of the VIVACE Electrosurgical System.

Tests were performed on the Vivace Electrosrugical System and its sterile disposable single use micro-needle cartridge. The biological safety of the device has been demonstrated through biocompatibility studies of all patient contact materials in accordance with the standards outlined in IS010993-1

Results of the clinical testing demonstrated that the VIVACE Electrosurgical System is safe and effective for its intended use. The micro-needle cartridge is supplied sterile and sterility conforms to a Sterility Assurance Level (SAL) of 10^{-6}. The supplied Instructions for Use provide the user with the applicable warnings and cautions during use. There are no new safety or effectiveness issues related to this device.

VIII. Clinical Summary

The study had 31 participants with 28 subjects completing all three sessions and are included in the final study analysis. The data were evaluated against baseline at 30 days, 60 days and 90 days by three, blinded, independent licensed physicians using the 9-point Fitzpatrick Wrinkle and Elastosis scale scoring methodology for the peri-oral and periorbital regions. The scores showed improvement over the 90 day period after treatments. Among the 3 blinded evaluators, by 2/3 evaluator agreement ($\geq$ 1 point change) criteria, 17 out of 28 (60.7%) subjects had one point improvement at 90 day follow up.

Adverse Events that occurred in greater than 5% of the subjects were Erythema (77.42%), Edema (19.35%), Edema (16.13%), and Sensitivity (6.45%). Adverse event cases decreased with each re-treatment phase for all AE types and were resolved within 24 hours. Overall adverse event rates were highest at the first treatment cycle, decreasing by a third after the second treatment and with little to no AEs reported after the third and final treatment (from 70.97% at treatment cycle 1 down to 6.45% at treatment cycle 3). Across treatments, each AE consistently decreased after the first, second and third (final) treatment cycles for every AE.

Most of the patients felt less pain overall through 3 treatment cycles. At 1st treatment cycle, for the peri-orbital wrinkle area, 9/28 subjects experienced pain at level 1-3 (32%) range, 12/28 at level 4 to 6 (43%) range, and 7/28 at level 7 to 10 (25%) range. During 3rd treatment cycle, 15/28 subjects reported experiencing pain at levels 1-3(53%), 12/28 at levels 4 to 6 (43%), and 1/28 at levels over 8 (3.5%). We hypothesize that the decrease in pain may be related to tissue coagulation and increased dermal thickness from initial exposure to RF energy treatment. During the 7 – 10 day interval, histological changes in the dermis may affect sensitivity during follow up treatment cycles with increase tolerance for RF energy.

The data shows gradual wrinkle class improvement at 90 days. The scores and change in wrinkle class demonstrate improvement in rhytids and in solar elastosis. The independent blinded evaluations support post treatment efficacy based on the Fitzpatrick Wrinkle Scores. All studied parameters suggest a favorable treatment profile of the VIVACE device to reduce wrinkles in the peri-orbital and peri-oral regions. The device showed moderate, but positive improvement in wrinkle severity and elastosis damage.

IX. Conclusion

The intended use of the VIVACE Electrosurgical System is substantially equivalent to the predicate device in intended use, design and RF technology. The clinical study demonstrates that the VIVACE functions as intended with no significant impact on the safety and effectiveness profile of the device for the treatment of facial wrinkles.

Data to support substantial equivalence to the predicate device was generated in a clinical study. The clinical study was designed to demonstrate the Vivace device is safe and effective for the treatment of facial wrinkles. Clinical data from a 31 patient US study using a validated scale, Fitzpatrick Wrinkle Severity Scale, supported substantial equivalence of the VIVACE to the predicate device for the percutaneous treatment of facial wrinkles in peri-oral and peri-orbital regions.